October 22, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. von Eschenbach:

The Committee on Oversight and Government Reform has been conducting oversight of the Food and Drug Administration (FDA). I am writing to request information relevant to agency's regulation of medical devices.

As you know, on October 15, 2007, Medtronic, Inc., voluntarily recalled its Sprint Fidelis leads which are components used in implantable cardiac defibrillators. An estimated 235,000 patients have Sprint Fidelis leads in their implantable cardiac defibrillators manufactured by Medtronic.[1] By the company's own estimates, 2.3% patients — or about 4,000 to 5,000 patients — with Sprint Fidelis leads will experience fractures in the leads.[2]

Some concerns have been raised about whether FDA required adequate pre-approval testing for these heart-device components. According to the *New York Times*, an FDA official stated that FDA did not require clinical trial testing of the Sprint Fidelis lead before approval.[3]

It is clear from the *New York Time*s article cited above that FDA has already formulated a plan to evaluate whether the testing of the leads that the agency has required to date is adequate to assess the safety of these devices.[4] I applaud FDA for promptly recognizing and taking steps

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[1] Meier, Barry, *In Data for Heart Devices, Parts Are a Blind Spot*, New York Times (Oct. 16, 2007) (online at http://www.nytimes.com/2007/10/16/business/16device.html).

[2] *Id.*

[3] Meier, Barry, *Tests of Heart Devices to Get Review*, New York Times (Oct. 18, 2007) (online at http://www.nytimes.com/2007/10/18/business/18device.html).

[4] *Id.*

to address what is apparently a serious shortcoming in the agency's approval process for these devices.

However, in an effort to gain a better understanding of the process by which FDA approved the Medtronic Sprint Fidelis leads, as well as other devices for life-threatening diseases and their components, the Committee requests that the agency respond to the following questions:

1. Please provide a chronology of agency actions related to approval of the Sprint Fidelis leads, including, but not limited to, the date of approval for the Sprint Fidelis leads, the PMA or supplement number under which the Sprint Fidelis leads were approved, and any subsequent agency actions or approvals related to the Sprint Fidelis lead.

2. There are 37 supplements listed on CDRH's website for the Medtronic Transvene Lead System PMA — the same PMA under which the Sprint Fidelis leads were approved. How many of these supplements address new components of the Transvene Lead System? How did FDA decide that the Sprint Fidelis leads were a new component of the Transvene Lead System as opposed to a new device? What distinguishes a new component from a new device?

3. Please provide the summary of the safety and effectiveness data upon which FDA based its approval of the Sprint Fidelis leads. Please also provide an explanation for why this information is not currently posted on FDA's website, as it is for many other PMA devices. Additionally, please provide an explanation for why FDA did not require Medtronic to submit clinical trial data to support the safety and effectiveness of the Sprint Fidelis leads.

4. Please describe the process by which FDA approves all defibrillator leads. Specifically, please explain whether FDA would approve a defibrillator lead under a distinct PMA or as a supplement to a PMA for another device.

5. Please provide information relating to when and how FDA first became aware of the potential fracture problem and when FDA first proposed that action be taken on this problem to the company. Please also describe the events leading to the voluntary recall, including any communications FDA had with the company regarding the recall and the dates of such communications.

6. Please provide the number and types of adverse events that have been reported to FDA since the introduction of these devices, by month. Were all adverse events related to fracture problem submitted in a timely manner?

7. In the aftermath of the problems found with the Guidant implantable defibrillators, did the agency create any guidances or policies for the oversight of these critical devices? Are there any guidances or policies on the approval of defibrillator leads?

8. In an October 15th letter to physicians, Medtronic refers to two studies: the Returned Product Analysis and the Medtronic System Longevity Study.[5] Did Medtronic provide data from these studies to FDA? If so, when were these data turned over to FDA? If not, why not?

9. Did FDA review any direct to consumer advertisements for the Sprint Fidelis leads or any Medtronic device including such leads?

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. Enclosed with this letter are instructions on how to respond to the Committee's document request.

If you have any questions regarding this request, please contact Stephen Cha at (202) 225-5056.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member

[5] Letter from Medtronic to physicians (Oct. 15, 2007) (online at http://www.medtronic.com/fidelis/physician-letter.html).